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Identifying Implementation Strategies That Address Barriers and Facilitate Implementation of Digital Interventions in HIV Primary Care Settings: Results from the Pilot Implementation of Positive Health Check

Brittany A. Zulkiewicz[1], **Olivia Burrus**[1], **Camilla Harshbarger**[2], **Alexa Ortiz**[1], **Bryan R. Garner**[1], **Megan A. Lewis**[3]

[1]RTI International, 3040 E. Cornwallis Rd., Research Triangle Park, NC 27709, USA

[2]Centers for Disease Control and Prevention, Atlanta, GA, USA

[3]RTI International, 119 S. Main St., Suite 220, Seattle, WA 98104, USA

Abstract

We used the 1-month pilot implementation of Positive Health Check, a brief web-based video counseling intervention that supports patients with HIV attending HIV primary care clinics, to exemplify how studying implementation strategies earlier in the evidence-generation process can improve implementation outcomes in later pragmatic trials. We identified how implementation strategies were operationalized and the barriers and facilitators these strategies addressed using multiple data sources, including adapted implementation procedures and weekly structured interviews conducted with 9 key stakeholders in 4 HIV primary care clinics. Nineteen of 73 discrete implementation strategies for clinical innovations were used in the pilot implementation of Positive Health Check. Clinic staff reported 17 barriers and facilitators related to the clinic environment, patient population, intervention characteristics, and training and technical assistance. Identifying the link between strategies, barriers, and facilitators helped plan for a subsequent larger multisite pragmatic trial.

Keywords

Implementation strategies; Digital interventions; HIV primary care; Pragmatic trials; Pilot studies

Introduction

Implementation strategies are “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” [1]. To date, the implementation strategies literature has focused largely on developing categorizations, reporting standards, and definitions of implementation strategies [1–3]; and systematically evaluating strategies for the dissemination and implementation of clinical guidelines [4], evidence-based treatment practices [5], and self-management support for chronic conditions

✉Megan A. Lewis, melewis@rti.org.

[6]. Given the focus in implementation science on the uptake of interventions that have proven effectiveness, it is not surprising that the main research focus in this area is how implementation strategies can be used to facilitate the translation of evidence to practice. However, in this paper we highlight that studying implementation strategies much earlier in evidence generation may help improve subsequent implementation studies and the generation of evidence downstream. We used the pilot implementation evaluation of Positive Health Check (PHC) [7], a brief web-based video counseling intervention for people with HIV (PWH) attending HIV primary care clinics, to examine the potential benefit of studying implementation strategies in preparation for a pragmatic [8, 9] type 1 hybrid trial [10]. Type 1 hybrid trials have a primary aim of evaluating an intervention's effectiveness with a secondary aim of understanding the context for implementation. The PHC evaluation trial has a primary aim of evaluating the effectiveness of PHC on improving patient outcomes and a secondary aim of assessing implementation context.

Successful implementation strategies are thought to improve key implementation outcomes, including acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability [11]. The Expert Recommendations for Implementing Change (ERIC) project has identified through expert consensus 73 discrete implementation strategies for clinical innovations [2, 3]. Clinical innovations are evidence-based practices and interventions for clinical settings that have not yet been integrated into practice. These discrete strategies can be combined to create complex strategies that target multiple levels or facets of implementation [3]. Although these implementation strategies were originally identified in the context of disseminating evidence-based practices and clinical innovations, we found that many are applicable early in the process of evidence generation for interventions that will be embedded in clinic workflows.

Three points underscore the importance of considering implementation outcomes early in the evaluation of interventions. First, evaluation outcomes can be confounded by poor implementation. Interventions that are poorly integrated into the organization's workflow may not be implemented with fidelity. Second, if effectiveness outcomes are confounded by suboptimal implementation and the intervention is deemed ineffective, interventions that may have the potential to be effective will never be disseminated. Third, effective interventions that are difficult to implement will not be adopted and will not reach their target populations. Intervention developers can use pilot evaluations as an opportunity to refine interventions or implementation strategies to facilitate better testing in larger trials and future dissemination.

Implementation strategies are essential for addressing contextual barriers to implementation that intervention design cannot address. To facilitate implementation, we designed PHC in consultation with a technical panel of HIV providers [7, 12]; completed a 4-week pilot implementation to assess the acceptability, feasibility, and appropriateness of PHC in primary care settings [13, 14]; and are currently conducting a pragmatic type 1 hybrid trial (https://clinicaltrials.gov/ct2/show/NCT03292913). The PHC pilot implementation provided a valuable opportunity to test and refine implementation procedures and strategies because suboptimal implementation during the current trial could lead to poorer implementation and clinical outcomes [15]. Suboptimal implementation is of particular concern in a pragmatic

trial in which participating organizations are given more freedom over implementation than in highly controlled efficacy trials.

In this paper, we describe how we operationalized and piloted implementation strategies for a pilot implementation of PHC [7, 13, 14]. Harshbarger et al. [14] found that although PHC pilot clinics perceived PHC as appropriate, feasible, and acceptable, some barriers negatively affected these implementation outcomes. This paper builds on Harshbarger et al. [14] by identifying all implementation barriers and facilitators experienced by pilot clinics using additional data sources and by examining the implementation strategies that were related to those barriers and facilitators. This paper contributes to the implementation strategies literature by describing how strategies that were originally identified to support implementation of evidence-based interventions and clinical innovations can be operationalized to support the implementation of digital interventions in HIV primary care clinics early on in the evidence-generation process.

Digital interventions use computer technology, including the Internet, mobile phones, and portable tablet computers, to promote behavior change [16]. PHC builds on previous digital interventions that have been shown to reduce sexual risk behaviors [17–19] and improve medication adherence [18, 20] and viral load suppression [18]. As evidence accumulates on the efficacy of digital interventions to support PWH [21], use of these interventions in health care settings will likely increase. A significant barrier to the success of PHC and other digital interventions designed for clinical settings is the challenge of integrating digital interventions into the complex workflows of primary care clinics [22, 23]. Thus, the understanding of useful implementation strategies could facilitate the use of these interventions in practice settings and support better testing of these interventions.

To date, no published literature describes implementation strategies for digital interventions and how they can be used to plan for pragmatic trials. This paper aims to fill that gap by describing how implementation strategies were operationalized during a 1-month pilot of the digital intervention PHC in 4 HIV primary care clinics. Our research questions are (1) what barriers and facilitators were identified during the pilot implementation? (2) what implementation strategies were used to implement PHC? and (3) how did these strategies relate to barriers and facilitators?

Background

In preparation for a pragmatic multisite type 1 hybrid trial, a 4-week pilot implementation of PHC was conducted in 4 clinics that provided primary care to PWH. The purpose of this pilot was threefold: (1) to investigate the feasibility of integrating PHC into the workflows of HIV primary care clinics, (2) to troubleshoot technologies that support the PHC digital platform, and (3) to create and refine implementation procedures and develop technical assistance (TA) materials to be used in the subsequent trial.

Pilot Implementation Settings

The clinics were located in diverse settings and served diverse patient populations. Clinic A was a rural, nonprofit clinic serving 257 PWH. At Clinic A, 87.0% of patients were black

or African American, and 60.0% were male. Clinic B was a nurse-managed, ambulatory, and multispecialty clinic in an urban setting serving 140 PWH. At Clinic B, 15.0% of patients were Hispanic or Latino, 60.0% were black or African American, and 60.0% were male. Clinic C was an academic medical center in a suburban location serving 1,927 PWH. At Clinic C, 58.8% of patients were black or African American, 7.3% were Hispanic or Latino, and 71.0% were male. Clinic D was an ambulatory clinic and primary care and specialty care practice located in a suburban and urban location. Clinic D served 1,166 PWH, 70.7% of whom were black or African American, 10.0% were Hispanic or Latino, and 70.8% were male.

PHC Intervention

PHC is a brief, web-based counseling intervention that uses "video doctors," fictitious providers portrayed by actors, to deliver individually tailored messages designed to improve medication adherence and, ultimately, viral load suppression, early antiretroviral therapy initiation, retention in care, and sexual risk behaviors. The intervention also offers modules on safe injection drug use and the prevention of mother-to-child HIV transmission. After these core modules, patients are offered access to an electronic or hard copy of their patient handout and pertinent resources in "Extra Info." A description of how the intervention was developed is detailed in previous articles [7, 13, 14]. In addition, PHC offers an accompanying Clinic Web Application (CWA) to monitor usage via data output from the intervention (e.g., number of users who completed PHC, number of handouts delivered to patients).

Pilot Implementation

The research team partnered with key staff at each site to implement PHC, including the clinic champion (a provider or research director responsible for obtaining approval for the study and generating buy-in from clinic staff) and at least 1 onboarder (an individual responsible for recruiting and onboarding patients to use the intervention). Two liaisons from the research team were assigned to each site to train staff, provide TA, and conduct site visits. The TA provided to clinics is shown in Table 1. Preimplementation activities involved collecting information about the clinics, their workflows, and their plans for implementation. Launch preparation during the site visit included confirming clinic layout to embed PHC in the workflow and reviewing implementation protocols. Implementation activities included tailoring implementation materials for each site and providing TA.

Methods

Data Sources from the Pilot Implementation

We used multiple data sources from the pilot implementation to identify barriers and facilitators to PHC implementation and the strategies that address barriers and facilitate implementation. We collected and analyzed data from clinic staff interviews, site assessments, and study documentation.

Clinic Staff Interviews—We conducted 54 interviews with 9 clinic staff across the 4 clinics. The PHC onboarder and clinic champion at each site were interviewed because of

their involvement in PHC and their ability to provide relevant feedback. Each staff member was interviewed 6 times, including 1 face-to-face interview before implementation, 4 weekly interviews by telephone during implementation, and 1 wrap-up interview by telephone after implementation. Staff were asked about clinic preparedness; satisfaction with training; barriers and facilitators; contextual factors affecting implementation; appropriateness, acceptability, and feasibility of PHC; perceived sustainability; and suggestions for improvements for PHC. Four trained coders coded notes from the interviews using a topical codebook [14]. We used a framework analysis approach to identify themes by site, staff type, and time points [24].

Site Assessments—We reviewed assessments completed by the clinics' clinic champions and onboarders in preparation for the pilot implementation to identify potential barriers and facilitators. The clinic workflow assessment asked clinics to document the processes that occur during a typical patient visit and to assign key PHC pilot implementation roles to clinic staff members. The informational technology (IT) assessment asked each clinic to confirm that their IT infrastructure met the minimum requirements of (1) having Internet Explorer (9, 10, or 11) or Chrome (Version 34) installed on a clinic computer; (2) a minimum Internet download speed of 10 Mbps; (3) a minimum wireless connection of 802.11g, n, or ac; and (4) wireless routers that support 802.11g, n, or ac standards. The implementation tailoring worksheet collected information on potential clinic-specific adaptations to generic implementation procedures, as well as barriers and facilitators.

Study Documentation—We reviewed standard operating procedures for training, TA, and site visits and other documentation of interactions between the research team and clinic staff, including site visit and meeting notes, to identify implementation strategies used in the pilot implementation.

Operationalizing and Mapping PHC Strategies

Author BZ matched the activities used to support the pilot implementation of PHC that were identified by reviewing these data sources to the implementation strategies defined by Powell et al. [3]. Strategies were grouped according to the categorizations specified by Powell et al. [2]. Authors AO and OB independently reviewed the strategies and their operationalization for consensus.

To determine which facilitators and barriers the strategies addressed, we reviewed data sources such as the clinic assessments, including the tailoring implementation worksheet that detailed implementation barriers and facilitators. Author BZ determined which facilitators and barriers the strategy addressed; Authors AO and OB independently reviewed these associations for consensus.

Results

What Are the Implementation Barriers and Facilitators?

Clinic staff reported barriers and facilitators related to their clinic workflow, staff engagement, patient characteristics, physical and technological environments, and

intervention characteristics (shown in Table 2). All barriers and facilitators tied back to time and physical space constraints.

Clinic Workflow—The clinic workflow was a barrier at all sites. All sites reported that there was not enough time to complete PHC between the patient's arrival and when they saw their provider. The amount of time required to onboard patients was cited as a barrier and was exacerbated by the learning curve to implement PHC. Onboarders at Clinics A, B, and C felt that the onboarding process took less time as they became more comfortable with implementation.

Staff Engagement—Clinics A, B, and C reported engagement with staff not involved in implementation as both a barrier and a facilitator. The goal of staff engagement is to generate buy-in from all clinic staff to facilitate integration of the intervention into the clinic workflow. Integration includes accommodating workflow changes and partnering with implementation staff to recruit patients to use the intervention. At Clinic A, staff engagement facilitated implementation because the onboarder had generated buy-in by meeting with each provider and demonstrating PHC. At Clinic C, staff engagement was both a barrier and facilitator. Clinic C reported that high staff engagement allowed the onboarder, who was brought in exclusively for the pilot implementation, to become integrated into the clinic. However, the onboarder was not able to engage other clinic staff to allow the patients to complete PHC before being seen; as a result, patients at Clinic C had low PHC completion rates. Similarly, Clinic B reported that clinic staff had not come to an agreement beforehand regarding when patients should use PHC. As a result, patients were frequently interrupted while using PHC.

Technology and Digital Literacy—The digital literacy level of patients acted as both a barrier and facilitator to PHC. The password generation process in particular was a barrier during the onboarding process. For privacy reasons, PHC requires that patients generate complex passwords with a combination of symbols, numbers, and uppercase and lowercase letters. Staff at Clinics A, C, and D noted this was a time-consuming process because onboarders had to help patients come up with their own password. Additionally, Clinic D reported that the onboarder had to assist patients with PHC because they were not familiar with using tablet computers. Clinic B did not find password generation to be a barrier because they had a younger patient population with a higher level of digital literacy. Digital literacy facilitated implementation at Clinic C because patients were routinely approached to use tablet interventions for research.

Physical Environment—At Clinics B and C, patients were frequently interrupted while using PHC to meet with nurses and providers and receive other services. These interruptions were attributed in part to insufficient physical space. At Clinic B, providers assumed that patients were available because they were in an exam room. Clinic B required that patients use PHC in exam rooms because of concerns about privacy in a communal waiting room and the impracticality of using the clinic conference room as an alternative. At Clinic C, providers could not delay seeing patients to allow them to complete PHC because of a

shortage of exam rooms. In contrast, Clinics A and D had extra space, which allowed patients to use PHC without disruption.

The physical environment also hindered delivery of handouts at Clinics B and C. Fax machines were located in inconvenient spaces that prevented the onboarder from either knowing that the handout was printed or added substantial time between printing and delivery so that patients were already seeing their provider.

Technological Environment—The technological environment was intermittently a barrier to implementation at Clinics A, B, and C. At Clinic C, handout printing was delayed by up to 40 minutes because of an overburdened fax machine. As a result, patients did not receive their handouts before their appointment. At Clinics B and C, user error, poor Internet connections, or other technological issues at times required the onboarder to intervene and reset the tablet or PHC.

Training and Technical Assistance—Onboarders at all clinics reported being satisfied with the training and TA that they received. Providers at Clinics A, C, and D reported being satisfied with the in-person training; the provider and clinic champion at Clinic B felt that they would need to review the training materials again to determine their satisfaction with training.

What Implementation Strategies Were Used to Implement PHC?

Of the 73 discrete strategies identified by Powell et al. [3], we used 19 strategies from the plan (8 strategies), educate (5 strategies), finance (1 strategy), restructure (1 strategy), and quality management (4 strategies) categories specified by Powell et al. [2] in the pilot implementation of PHC. We describe the operationalization of each strategy used in the PHC pilot implementation in Table 3.

Plan—We used 8 planning strategies to prepare clinics for implementation. Before establishing contracts, each clinic completed a written assessment that asked for the percentage of their patients who met the criteria for the intervention's target populations (Strategy 1). The purpose of this assessment was to confirm that PHC would be relevant to the clinic's patient population and that the clinic was representative of sites that would potentially implement PHC during dissemination. After each clinic completed the application, we established a contractual agreement that required the clinic to implement PHC for 4 weeks (Strategy 8). During this process, a clinic champion was identified at each clinic (Strategy 6). The champion assisted with receiving the necessary approvals and identifying staff who would implement the intervention.

During the preimplementation period, the clinic staff responsible for implementing the intervention completed 3 written assessments that were designed to assess for readiness and identify barriers (Strategy 2) and to promote adaptability of intervention procedures (Strategy 7). We intended to conduct a quick confirmation of these assessments at the in-person site visits (Strategy 5); however, at the first site visit it became clear that the written assessments were not sufficient to capture the clinic's workflows accurately and

to identify potential barriers. As a result, clinic staff at each site completed a physical walk-through with TA staff during which they discussed barriers, patient and staff movement through the clinic, and implementation procedures. Based on the information gathered from the assessments and site visit, we generated a tailored implementation plan for each clinic (Strategy 3).

Educate—We used 5 educate strategies to train staff implementing the intervention and to educate other staff members about the intervention and pilot implementation. We developed educational handouts and an intervention package that included an in-depth implementation manual and a 1-page quick guide that described key implementation steps (Strategy 9). During staff interviews, staff reported frequently using the quick guides, while the in-depth manual was used only occasionally for reference. These materials and others were distributed in physical and electronic forms at the site visit (Strategy 10). Initially, we planned to host in-service trainings for all clinic staff during each site visit (Strategy 11). However, it was not possible to host this training at all clinics because of scheduling conflicts. To train implementation staff, we had developed PowerPoint presentations to describe the intervention and implementation procedures as part of the intervention package. At the first site visit, however, we found that it was more effective and engaging to conduct walk-through and role-playing exercises with staff as part of a dynamic training approach with the PowerPoint and intervention package as reference materials (Strategy 13). Subsequent site visits used the dynamic training approaches.

Restructure—We used 1 restructure strategy to provide clinics with the equipment necessary to implement PHC (Strategy 14). We initially intended to provide all clinics with 3 iOS or Android tablets. We ultimately supplied all sites with privacy screens and headphones to maintain patient privacy when the intervention was used in a communal space. We also provided hotspots to 2 sites to supplement insufficient Internet bandwidth or dead zones and wireless printers to 2 sites to address issues with fax machines.

Finance—We used 1 finance strategy to fund and contract for the clinical innovation (Strategy 15). This strategy did not change during the pilot implementation.

Quality Management—We used 4 quality management strategies to monitor implementation and provide TA. The centralized TA team structure (Strategy 16) allowed liaisons to identify common barriers across sites and to share solutions that were implemented at 1 site with other clinics that were experiencing the same challenge (Strategy 17). We provided clinic staff with access to the CWA to monitor implementation fidelity and progress (Strategy 19). However, clinics rarely used the reporting and data export functions to examine implementation. The TA team purposefully re-examined implementation (Strategy 18) by using the data provided in the CWA and discussing implementation during the weekly interviews with key staff. The weekly interviews became an integral part of TA efforts because implementation barriers, adaptations, and solutions were frequently discussed during these calls.

How Did Implementation Strategies Relate to Barriers and Facilitators?

Providing Clinics with the Appropriate Equipment Was an Important Implementation Strategy to Address Environmental Barriers—Insufficient wireless Internet bandwidth, wireless Internet dead zones, overburdened fax machines, inconvenient access to fax machines, and limited availability of private spaces for patients to use the intervention were barriers addressed by providing clinics with the appropriate equipment. However, not all environmental barriers could be addressed. For example, patients at Clinics B and C still experienced disruptions while using PHC because of the limited availability of space.

Staged Implementation Scale-Up, Centralized TA, and Capturing and Sharing of Local Knowledge Allowed Strategies to be Refined and Barriers to be Proactively and Quickly Addressed—Implementation at the clinics was staggered by approximately 1 week. This allowed us to refine implementation strategies, such as introducing dynamic training and providing wireless printers and hotspots, to better prepare staff at subsequent sites. This approach combined with centralized TA also allowed us to share knowledge between sites. For example, Clinics A and D experienced barriers with low digital literacy. Clinic A developed a script to help patients generate acceptable passwords; this script was shared with all other sites through liaisons and implemented at other clinics.

Quality Management Strategies Were Important for Providing Sufficient TA—All of the quality management strategies used in the pilot implementation contributed to the sufficient TA the clinics received. Through the centralized TA strategy, liaisons were able to identify and respond to clinic TA needs with in-depth knowledge of the clinic context. Lessons learned from 1 clinic were applied to other clinics through the centralized TA. Purposefully re-examining the intervention during weekly interviews and using CWA data were important opportunities for liaisons to identify the clinics' TA needs. Implementation staff discussed barriers and adaptations made to implementation procedures on the weekly calls; liaisons helped troubleshoot barriers and suggest alternative adaptations when changes to procedures threatened fidelity. Using the CWA, liaisons were able to examine the number of patients using PHC and the extent to which it was implemented with fidelity. Liaisons used these metrics to work with clinic staff to identify barriers.

Sufficient Training Did Not Eliminate a Learning Curve—We found dynamic training to be an effective and engaging method of training implementation staff. In the interviews, implementation staff at all sites reported having received sufficient training. However, despite adequate training, 3 of the 4 sites still experienced a learning curve during the pilot implementation period.

Promoting Adaptability Had a Limited Impact on Overcoming Workflow Barriers due to Innate Intervention Characteristics—We promoted adaptation of implementation procedures as a way to address clinic workflow periods throughout the pilot implementation. TA was often focused on how to address these barriers through adaptations. Despite these efforts, all clinics reported having insufficient time for patients to use PHC before their appointment in part because of intervention characteristics. Three

clinics reported the length of time required for the onboarding process as a barrier, and 3 clinics reported the time required to generate the password as a barrier.

Staff Engagement Is Important for Overcoming Clinic Workflow Barriers, But the Impact of the Implementation Strategies Was Limited—Changing the clinic workflow to accommodate PHC required engagement from other clinic staff (e.g., providers and staff checking in patients). Implementation staff reported that low engagement from clinic staff hindered implementation at 2 clinics and high engagement facilitated implementation at 2 clinics. The impact of our educational outreach strategy was likely limited. Although a contractual agreement was established at all sites, 2 sites reported insufficient engagement to prioritize the intervention in the clinic workflow. The implementation staff at the 2 clinics that reported high staff engagement reported building staff buy-in outside of the in-service training offered during the site visits.

Discussion

We used the implementation strategies generated via the ERIC project [3] to analyze those used in a pilot implementation of PHC in preparation for a larger multisite pragmatic type 1 hybrid trial. Our goal in this paper was to understand if strategies previously identified for implementing evidence-based interventions and clinical innovations also applied to our PHC pilot implementation and if they addressed barriers and facilitators.

Many of the barriers experienced by the 4 clinics that participated in the PHC pilot implementation related to time and physical space constraints. The barriers included busy clinic workflows, intervention characteristics (e.g., time required to onboard patients), patient characteristics (e.g., digital literacy), and technological and physical environments (e.g., poor Wi-Fi connections and lack of extra exam rooms). We provided training and TA to support pilot implementation efforts, which included multiple implementation strategies identified by Powell et al. [2, 3], as well as contracting and funding as a way to engage all clinic staff in the implementation of the intervention. Staff engagement is an important strategy for addressing time and physical constraints because staff who are invested in the success of the intervention may be more likely to accommodate the necessary changes in the clinic workflow and physical spaces to overcome these barriers.

We identified 19 implementation strategies used in the PHC pilot implementation study that centered around plan, educate, restructure, finance, and quality management as described by Powell et al. [2]. The Waltz et al. [25] grouping of implementation strategies from the ERIC project used in this pilot implementation related to using evaluative and iterative strategies, providing iterative assistance, adapting and tailoring strategies, developing stakeholder interrelationships, training and educating stakeholders, and changing infrastructure. Regardless of which categorization of implementation strategies is used, we found that many related to planning/evaluative and iterative strategies. Although we provided sites with training and TA, unanticipated challenges surfaced once implementation started. This points to the importance of the strategies for planning and also iteration. In addition, all implementation strategies were tailored to each clinical site, which is important for addressing contextual barriers.

Several important points emerged when we examined the link between PHC implementation strategies and barriers and facilitators. For example, training and TA activities contributed to multiple strategies, likely because these activities provide many generalized benefits to implementation. This conclusion is echoed in previous research that concluded TA needs are central to the successful implementation of couple-based HIV testing and counseling in the United States [26]. In contrast, other strategies had more specific benefits but addressed fewer barriers. For example, the barrier of having a learning curve was related to only 2 strategies: scaling up stage implementation and making training dynamic. This finding suggests that it may be worthwhile to identify and prioritize implementation strategies useful for ameliorating specific barriers. The refinement of the links between strategies that may provide a generalized benefit and those that provide more specific benefits will help advance the understanding of strategies as mechanisms of change that support implementation [27, 28]. As the field advances and more evidence accumulates about how strategies actually work, their use will lead to more effective implementation, particularly for complex, multilevel interventions integrated into practice and clinical settings [29]. This is an important topic for future research.

We found several strategies helpful to facilitate implementation. The strategy to distribute educational materials included recording and posting trainings. TA and implementation staff can refer to these in future evaluation and dissemination efforts. Additionally, the recordings guard against quality issues that emerge with staff turnover, which occurred even during our 1-month pilot period. Tailoring strategies is important because all clinics face unique barriers and facilitators. Additionally, clinic staff have different backgrounds and skill sets. Some may be more comfortable implementing a digital intervention than others. We found that being proactive about identifying needed adaptations facilitated implementation. Clinics often make adaptations without informing evaluators or TA providers, which if not done properly can diminish fidelity. Although greater flexibility in implementation may be useful in some cases, we found clinics that took this approach reported fewer patients completing the intervention, thus limiting the reach of the intervention. For optimal implementation outcomes, TA providers must balance flexibility of implementation with fidelity to the intervention. Previous research examining implementation of HIV linkage and retention programs found that flexibility and allowing for local adaptation facilitated implementation and helped the intervention better fit the needs of patients and clinics [30].

Although PHC was developed with extensive input from a technical panel of HIV care providers [7], user-centered intervention design did not eliminate barriers to integrating PHC into HIV primary care clinic workflows. This finding suggests that implementation strategies need to be considered in each study or context until research is better able to identify the causal pathways linking implementation strategies to outcomes [27, 28]. As we found in this pilot, clinic workflows are governed by strict and competing requirements, so implementing even an intervention that requires minimal staff labor can be challenging.

Lessons Learned for the Evaluation Trial

The lessons learned from the pilot implementation have been incorporated into the pragmatic trial. For example, training materials and procedures were revised based on

feedback from the pilot. Adaptations and solutions used during the pilot to address barriers were incorporated into assessments and the implementation manual. The dynamic training procedures were used at all clinics, and implementation was staggered by several days. To increase engagement of clinic staff, staff were offered the opportunity to use the intervention during an in-service training. Wireless printers and hotspots were offered to all clinics in the evaluation from the onset of implementation because of the benefits given to pilot clinics. TA was centralized further, with 2 liaisons working closely with all 4 evaluation clinics to facilitate sharing of lessons learned. Because of the importance of the weekly interviews in providing sufficient TA during the pilot implementation, the liaisons have standing biweekly meetings with each clinic to touch base. As a result of the pilot, PHC was converted into a stand-alone app in addition to a browser-based version to bypass technical issues c by the clinics and technological barriers that would hinder future implementation dissemination efforts, such as software upgrades. In addition, a new feature was built into the CWA to allow clinic staff to better monitor patient progress navigating through the intervention. Because of the lessons learned in the pilot, the research team has been better able to leverage implementation strategies to address barriers and to enhance facilitators of implementation.

Limitations

This study has several limitations. First, the strategies identified in this paper may not be an exhaustive list of all strategies used during the pilot. Implementation staff at each site likely used their own strategies to implement PHC. Although we asked staff during weekly interviews questions about implementation, we did not ask them to choose from the list of the implementation strategies described in the literature. It is possible that we did not capture the universe of strategies they used in the pilot implementation. Future research could benefit from using a more structured mapping of implementation strategies, even in the planning phase [31]. Second, the goal of the pilot implementation was to plan for a larger pragmatic trial, so the analysis of implementation strategies as they relate to the barriers and facilitators was a secondary analysis. The consequence of this is that we did not use Proctor et al.'s [1] full framework, which recommends delineating the actors, action targets, dose, temporality, expected outcomes, and justification for each strategy. Future research that examines these dimensions could provide finer-grained information about strategies and their link to implementation outcomes. Despite not using the full framework, our analysis was useful to the planning and implementation of the subsequent trial. Finally, the pilot implementation period lasted only 4 weeks. We found that many changes took place during that brief time, and it is likely that the strategies may have changed if the clinics had more time to implement the intervention. Other studies that have mapped implementation strategies to their use in implementation of complex interventions have found that time is an important factor related to strategy use [32].

Conclusions

In summary, we found the study of implementation strategies in an early pilot implementation to be useful in planning for a larger trial. This is particularly true because PHC is a digital intervention that needed to be integrated into the clinic workflow and drew on resources such as Wi-Fi speed, IT infrastructure, and the digital and computer literacy of

both clinic staff and patients. The additional time needed to onboard patients compounded time constraints for implementing PHC in the clinic environment. Using implementation strategies to plan implementation and to address implementation barriers and facilitators early in the evidence-generation process offers the benefit of improving the conduct of pragmatic trials and determining whether implementation is feasible in practice.

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Table 1

Pilot implementation training and TA activities

Preimplementation	Launch	Implementation
• Administered assessment to characterize clinics and their patient populations • Administered clinic workflow assessment to evaluate services offered, procedures completed during primary care visits, and workflows • Administered technological assessment to evaluate each clinic's technological capacity • Administered staffing assessment to determine which staff would fill key roles • Administered implementation worksheet to guide clinics through identification of barriers, facilitators, and adaptations at each step of PHC implementation • Reviewed basics of PHC and implementation procedures with key clinic staff • Engaged clinic champions to acquire necessary approvals, identify other key staff, and garner buy-in • Purchased equipment	• Completed a walk-through to document physical layout of clinic and clinic workflow • Evaluated clinic Wi-Fi network capabilities and tested PHC • Hosted educational session for all clinic staff, including experiencing PHC • Distributed educational handouts and other TA materials • Reviewed implementation binder and other training materials • Trained staff using role-playing exercises • Conducted a half-day soft launch with TA staff on site • Delivered and set up equipment	• Tailored implementation binders for each site • Shared lessons learned from other sites • Communicated FAQs and clarifications • Provided additional equipment as needed to resolve issues • Provided implementation TA through liaisons and PHC technical support through Centers for Disease Control and Prevention's Help Line • Monitored implementation progress through CWA • Weekly touchpoints

Table 2

17 barriers and facilitators in PHC pilot implementation

	Clinic A	Clinic B	Clinic C	Clinic D
Clinic workflow				
Insufficient time between arrival and appointment to complete PHC (−)	X	X	X	X
Disruptions to patients completing PHC (−)		X	X	
Staff engagement				
Could not engage staff to adapt workflow (−)		X	X	
High staff engagement (+)	X		X	
Physical environment				
Location of fax machines (−)		X	X	
Availability of private space (+)	X			X
Lack of private space (−)		X	X	
Technological environment				
Overburdened fax machines (−)			X	
Device errors (−)		X	X	
Internet connection (−)	X		X	
Patient characteristics				
High digital literacy (+)		X	X	
Low digital literacy (−)	X			X
Intervention characteristics				
Onboarding process (−)	X	X	X	
Password requirements (−)	X		X	X
Learning curve (−)	X	X	X	
Training and TA				
Sufficient training (+)	X	X	X	X
Sufficient TA (+)	X	X	X	X

(+) denotes factors that were facilitators in the pilot implementation. (−) denotes factors that were barriers in the pilot implementation

Table 3

Implementation strategies, their operationalization, and links to barriers and facilitators

Strategy name	PHC operationalization	Related barriers and facilitators
Planning		
Conduct local needs assessment	• Participating clinics completed a clinic assessment before implementation to confirm that the clinic served a sufficient number of patients who could benefit from the intervention	High staff engagement (+)
Assess for readiness and identify barriers	• Before the site visit, each site completed a workflow assessment to document the clinical workflow from patient arrival to patient checkout and to identify potential barriers and facilitators • Before the site visit, each site completed a staffing assessment to identify staff who would implement the intervention • Before the site visit, each site completed a technical assessment to determine whether the clinic's Wi-Fi network could support PHC, and Wi-Fi speeds were tested on site • We developed a tailoring worksheet that identified potential adaptations that could be made to implementation of the intervention. Sites completed the worksheet to identify any additional barriers and facilitators that would need to be addressed • We confirmed written assessments in person at a site visit. We worked with clinic staff to conduct a walk-through of the patient experience and modeled implementation of the intervention at the clinic to identify barriers • During each site visit, we created a map of the clinic's physical layout to identify and document physical barriers, including Wi-Fi dead-spots	Sufficient training (+) Sufficient TA (+)
Develop a formal implementation blueprint	• After the site visits, we customized the implementation manual to reflect each site's tailored implementation procedures. This document served as a formal implementation blueprint and detailed the development and purpose of PHC, the roles and responsibilities of implementers, and the operationalization of PHC implementation	Sufficient training (+) Sufficient TA (+)
Tailor strategies to overcome barriers and honor preferences	• We customized training strategies to clinic context and staff skills • We customized TA to staff experience and skills • We customized the equipment provided to meet technical requirements	Sufficient training (+) Sufficient TA (+)
Stage implementation scale-up	• We conducted a 1-day soft launch at each clinic with TA staff on-site to assist with questions and troubleshoot technical and implementation issues. Each site onboarded at least 2 patients • We staggered implementation at clinics so that lessons learned from 1 site could be applied to others	Learning curve (−) Onboarding process (−) Sufficient training (+) Sufficient TA (+)
Identify and prepare champions	• Each site identified a provider to serve as the clinic champion. The champion participated in trainings, attended meetings with TA liaisons, orchestrated site visits, and completed weekly interviews • We identified a clinic champion and trained them on the purpose of PHC and the pilot trial • We gave clinic champions all support needed, including written materials and demonstrations, to support their engagement efforts	Could not engage staff to adapt workflow (−) High staff engagement (+)

Strategy name	PHC operationalization	Related barriers and facilitators
Promote adaptability	• We promoted adaptations to implementation procedures in the implementation manual and tailoring worksheet	Clinic workflow (−) Insufficient time between arrival and appointment to complete PHC (−) Disruptions to patients completing PHC (−)
Obtain formal commitments	• We established contractual agreements with each clinic that required PHC be implemented for 4 weeks	High staff engagement (+)
Educate		
Develop effective educational materials	• We created branded educational materials for training and staff education, including: – Brochures for staff and providers describing PHC, its purpose, and the pilot implementation – A PowerPoint presentation describing the purpose and development of the intervention and the pilot implementation – Video demonstrations of the intervention – Implementation manuals – Quick guides	Sufficient training (+) High staff engagement (+)
Distribute educational materials	• We distributed educational materials through several channels during the preimplementation period and at launch: – Printed handouts were given to staff at site visits – Copies of digital handouts were provided to onboarders – Recordings of trainings and demonstrations were accessible on YouTube video channel – Physical and electronic copies of the implementation binder were provided to key staff; digital files were distributed on USB drive	Sufficient training (+)
Conduct educational outreach visits	• During the site visit, we hosted an educational lunch meeting with all clinic staff to introduce PHC and demonstrate the intervention	Could not engage staff to adapt workflow (−) High staff engagement (+) Sufficient training (+)
Conduct ongoing training	• We implemented ad hoc trainings to supplement training or address new issues	Sufficient training (+) Sufficient TA (+)
Make training dynamic	• We created a dynamic training process using: – Written materials – In-person walk-throughs – Role playing – Recorded webinars	Learning curve (−) Sufficient training (+)
Restructure		

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Strategy name	PHC operationalization	Related barriers and facilitators
Change physical structure and equipment	• We provided tablets, privacy screens, and headphones • We provided wireless printers • We provided hotspots for wireless Internet access	Location of fax machines (−) Lack of private space (−) Overburdened fax machines (−) Device errors (−) Poor Internet connection (−)
Finance		
Fund and contract for the clinical innovation	• We established subcontracts with each clinic • We funded labor and materials costs for participation in the pilot implementation; in return, clinics were mandated to implement PHC for 4 weeks	Staff engagement (+)
Quality management		
Centralize TA	• We established a small TA team to serve as liaisons between the larger research team and sites, with each site working directly with 2 liaisons from the TA team	Sufficient TA (+)
Capture and share local knowledge	• Through the centralized TA team, we shared successful solutions and adaptations to common barriers and answers to FAQs between clinics	Low digital literacy (−) Sufficient TA (+) Password requirements (+)
Purposefully re-examine the implementation	• We monitored implementation progress through the CWA • We discussed challenges and solutions with clinic staff	Sufficient TA (+)
Develop tools for quality monitoring	• We provided the CWA to monitor patient progress and onboarding history • We developed data export functions to allow analysis	Sufficient TA (+)

(+) denotes factors that were facilitators in the pilot implementation. (−) denotes factors that were barriers in the pilot implementation